UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS PRODUCTS LIABILITYLITIGATION

Master File No. 2:12-MD-02327
MDL No. 2327

THIS DOCUMENT RELATES TO THE FOLLOWING PLAINTIFFS:

Joseph R. Goodwin
U. S. District Judge

Christin Wiltgen
Case No. 2:12-cv-01216

Laura Waynick
Case No. 2:12-cv-01151

Denise Burkhart
Case No. 2:12-cv-01023

Debra A. and Donald Schnering
Case No. 2:12-cv-01071

Karen Bollinger
Case No. 2:12-cv-01215

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE THE TESTIMONY OF KIMBERLY KENTON, M.D., M.S.

I. PRELIMINARY STATEMENT

Now come Plaintiffs seeking to exclude, or to limit in the Court's discretion, and as set forth herein, the expert testimony of Dr. Kimberly Kenton, M.D., M.S. ("Dr. Kenton"), pursuant to Federal Rule of Evidence ("Rule") 702 and the standards set forth by the United States Supreme Court in *Daubert v. Merrell Dow Pharms. Inc.* 509 U.S. 579 (1993) and as adopted by the Fourth Circuit. *See Bryte v. Am. Household, Inc.*, 429 F3d 469, 476 (4th Cir. 2005)(federal law governs

the admissibility of expert testimony). Plaintiffs seek to exclude any and all opinions proffered by Dr. Kenton in her expert report dated September 15, 2015[1] and during her deposition testimony on February 18-19, 2016[2],[3] as to the following:

- any and all opinions regarding the chemical, physical, or biomechanical makeup of the TVT retropubic sling ("TVT") manufactured and marketed by Defendant, Ethicon, Inc. ("Ethicon") and/or any of the TVT's component parts, including but not limited to, any polypropelene mesh because Dr. Kenton is not qualified to render such opinions;
- any and all opinions proffered by Dr. Kenton that there is no discernible difference between mechanical-cut and laser-cut TVT devices because 1) she is not qualified to render any such opinions and because 2) to the extent the Court does not find her unqualified, Dr. Kenton relied on data that lacked relevance and/or was otherwise unreliable to support her opinions; and
- any and all opinions proffered by Dr. Kenton that women implanted with the TVT suffer chronic pain from the devices only rarely because Dr. Kenton grounded her opinions in poor methodology and failed to apply properly her own reliance materials stating that chronic pain can be caused by TVT devices;
- any and all opinions proffered by Dr. Kenton during her September 15, 2015 deposition related to an article authored by Dr. Jerry Blaivas and/or to any of the

[1] Rule 26 Report of Kimberly Kenton, M.D., M.S. Board-Certified, Female Pelvic Medicine & Reconstructive Surgery ("Kenton Report") is attached hereto as Exhibit A-1. Future citations will be in the form (Ex. A-1, ___).

[2] Relevant excerpts from the transcripts of Volumes I and II of the Videotaped Deposition of [Dr. Kenton] taken February 18, 2016 and February 19, 2016 ("Kenton Deposition") will be attached hereto as Exhibit B. Future citations will be in the form (Ex. B, ___:___ - ___:___).

[3] Both the Kenton Report and the September 15, 2015 deposition were submitted to this Court as part of the consolidated cases that preceded the current Wave 1 litigation. Plaintiffs previously moved to exclude or limit some of Dr. Kenton's opinions in the consolidated litigation as well.

source materials cited by Dr. Blaivas therein (at least as insofar as such relates to his article) because Dr. Kenton never read it.

In addition, as set forth herein, Plaintiffs now also seek to exclude, or limit in part, the opinions proffered by Dr. Kenton for the current litigation during her deposition testimony on March 25, 2016, as well as in the Rule 26 Report of [Dr. Kenton], M.S. Board Certified, Female Pelvic Medicine and Reconstructive Surgery dated March 1, 2016. ("Kenton Report 2.")[4] Following this Court's order, Plaintiffs substantially limited the time and scope of their deposition examination of Dr. Kenton on March 25, 2016, largely confining such to any materials in the Kenton Report 2 that relate to the TVT-O product manufactured and marketed by Ethicon. Therefore, to the extent that Dr. Kenton offers the identical and/or substantially same opinions in the Kenton Report and in the Kenton Report 2 regarding either Ethicon's TVT or TVT-O, Plaintiffs move that such opinions are subject to exclusion, or limitation in like manner, for the reasons set forth at pages 5-13 herein, along with citations to the record therein. (*See infra*, 5-13.) While the majority of Plaintiffs' points regarding the TVT are supported by citations to either the Kenton Report, the deposition testimony of February 18-19, 2016, or both, Plaintiffs argue that identical or substantially similar materials regarding the TVT in the Kenton Report 2 and in Dr. Kenton's testimony from March 25, 2016, are equally subject to exclusion or limitation for the same reasons, including that Dr. Kenton is unqualified to proffer them and that she has grounded her opinions in unreliable methodology.

To the extent that the Kenton Report 2 deals specifically with Dr. Kenton's opinions regarding the TVT-O device, Plaintiffs seek to limit or exclude those opinions at pages 13 - 15

[4] Relevant excerpts of Dr. Kenton's deposition of March 25, 2016 are attached hereto as Exhibit C and are cited to in the form (Ex. C, ___:___.) The Kenton Report 2 is attached hereto as Exhibit D and is cited to in the form (Ex. D, ___.)

herein (*see infra*, 13-15), generally citing to opinions proffered by Dr. Kenton during her deposition of March 25, 2016. Regarding these opinions, and as fully set forth herein, Plaintiffs move that Dr. Kenton's opinions should be limited at trial such that she cannot proffer opinions that contradict, limit, or counter opinions offered in her deposition of March 25, 2016.

II. FACTUAL STATEMENT – DR. KENTON'S QUALIFICATIONS[5]

Dr. Kenton is a board certified urogynecologist[6] who treats patients, performs surgeries,[7] and teaches and pursues other academic endeavors as a member of the faculty at the Northwestern University Feinberg School of Medicine.[8] She has utilized the full panoply of treatment options during the course of her career to treat patients suffering stress urinary incontinence ("SUI").[9] These options have included the Burch procedure, the use of native tissue slings, and the use of polypropylene mesh products, including the TVT, at various stages of her career.[10] Nevertheless, Dr. Kenton does not have any background, whatsoever, in the scientific, chemical or structural makeup of medical devices-- including Ethicon's TVT or TVT-O devices-- which are the subjects of the current litigation.[11]

III. LEGAL STANDARD

Rule 702 states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and

[5] Dr. Kenton's Curriculum Vitae ("CV") is attached hereto as Exhibit E. Cites to it will be in the form (Ex. E, ___).
[6] (Ex. A-1, 2) (Ex. E, 2-3)
[7] (Ex. B, 15:20-22)
[8] (Ex. E, 2)
[9] (Ex. B, 15:12-17:4)
[10] (*Id.*)
[11] Dr. Kenton has a Bachelor of Science degree in biology, a medical degree, and a Master of Science degree in clinical research design and statistical analysis. (Ex. E, 2.)

> (d) the expert has reliably applied the principles and methods to the facts of the case.

Rule 702.

The Supreme Court in *Daubert* assigned to district courts a "gatekeeping function" in determining whether expert testimony is both reliable and relevant and, thus admissible, under Rule 702. 509 U.S. 579. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152; *see also Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001)("Under [Rule] 702, trial judges act as gatekeepers to ensure that any and all scientific testimony . . . is not only relevant, but reliable,") (internal citations and quotations omitted.). Under both *Daubert*, 509 U.S. 579, and Rule 104(a) -- the statute imposing a duty on courts to decide preliminary questions regarding the qualifications of witnesses and/or the admissibility of evidence -- this Court must determine whether the requirements of Rule 702 are met before any expert testimony can be presented to the jury. *See, Cooper*, 259 F.3d at 199; (the district court determines whether the methodology employed by the expert is "scientifically valid" and whether that methodology is applicable to the facts in issue). While *Daubert* requires Rule 702 to be applied flexibly, unfettered admissibility is not the standard and "the proponent of the testimony must establish its admissibility by a preponderance of proof." *See Cooper*, 259 F.3d at 199 (citing to *Daubert*, 509 U.S. at 592 n. 10; *see also Hines v. Wyeth*, C. A. No. 2:04-0690, 2011 WL 2792436 at *2 (S.D.W.Va. July 14, 2011).).

IV. LEGAL ARGUMENT

A. DR. KENTON'S OPINIONS REGARDING THE TVT DEVICE, MANUFACTURED AND MARKETED BY ETHICON, MUST BE EXCLUDED OR LIMITED EITHER BECAUSE SHE LACKS THE QUALIFICATIONS TO RENDER THEM OR BECAUSE SHE HAS RELIED ON FLAWED METHODOLOGY OR INSUFFICIENT INFORMATION TO SUPPORT THEM.

1. Dr. Kenton Does not Qualify to Proffer Opinions Regarding the Chemical, Structural, or Biomechanical Makeup of the TVT[12] Device or of Any of its Component Parts and All of Her Opinions Related to Such Must be Excluded.

The Kenton Report includes numerous opinions that Dr. Kenton, as a practicing urogynecologist lacking training in chemical or structural engineering and/or in biomechanics, is simply unqualified to render. As such, her opinions must be excluded pursuant to Rule 702. *See* Rule 702 (an expert must be qualified by "knowledge, skill, experience, training, or education."). The opinions to be excluded are:

- that the properties of TVT mesh "are appropriate and desired for the intended use of treating [SUI]", including her opinion that studies indicate that the Prolene mesh in the TVT is preferable to mesh used in other sling devices; (*See* Ex. A., 14.)
- that "the way the mesh is cut [i.e. mechanical v. laser] does not seem to have a clinically significant impact on the mesh in actual women having surgery for [SUI];" (*id*.)
- that reducing the weight of the mesh while increasing the size of the pores in it would not have an impact on roping and curling of the mesh *in vivo*; *(id*.)
- that "[t]he TVT pore size allows for the intended tissue ingrowth which prevents pore collapse and does not foster shrinkage or contraction;" (*id*.)
- that the TVT is an "Amid Type 1/macroporous mesh," and, therefore, "generally accepted" for use as biomaterials; (*id*, 15.)
- that "[l]ighter weight, larger pore meshes have not been shown to be safer or more effective than TVT in clinical studies or RCT's;" (*id.)*

[12] To the extent that she offers them in the Kenton Report, the Kenton Report 2, or any related deposition testimony, Plaintiffs likewise move that Dr. Kenton also cannot offer opinions regarding the chemical, structural, or biomechanical make-up of the TVT-O device, or of any of its component parts, because she is not qualified to do so.

- that no clinical evidence shows particle loss when used *in vivo*; (*id*, 16.)
- that no data "support the theory that TVT degrades, loses particles, ropes, frays, or curls . . . or that there are clinically significant risks of degradation" and that any data purporting to show such is flawed; (*id*.)
- that "[t]he biomechanical properties and foreign body reaction of Prolene have been well-studied for almost 50 years as a suture and a mesh. Polypropylene is an appropriate material for use in clean contaminated surgeries;" (*id*, 17.)
- that "[n]o clinical evidence exists supporting the idea that the Prolene mesh used in TVT is cytotoxic and causes cell death *in vivo*, or is associated with malignancy that causes an increase in complications or a decrease in efficacy;" (*id*, 18.)
- that "it would be misleading to suggest that one could see signs of degradation that require SEM imaging or analytical tests to visualize or confirm;" (*id*) and
- that in her experience she has not "seen loose particles, fraying, or degraded mesh" or that she has not noticed a difference in properties between mechanical-cut and laser-cut mesh. (*Id*.)

Dr. Kenton would have this Court accept that she is a "surgeon-scientist who . . . has been involved in design." (*See* Ex. B, 192:13-15.) However, absolutely nothing in her education or training supports such a position. Just because she may have expertise in urogynecology does not render her capable of offering expert opinion outside her field. *See Smith v. Wyeth-Ayerst Laboratories Co.*, 278 F.Supp.2d 684, 697-98 (W.D.N.C. 2003) ("As Defendant points out, any expert including physicians, must have the specialized knowledge or skill in the specific area in which the testimony is proffered."). Dr. Kenton has no such specialized knowledge or skill, evidenced not only by her resume, but also by her testimony that she has no understanding of the

different propylene meshes used by device manufacturers, (Ex. B, 188:3-7), does not know whether antioxidants are used in the production of polypropylene mesh (*id*, 188:8-11), and does not know who manufactures the mesh Ethicon uses in the TVT. (*Id*, 187:24-188:2.) It is clear that Dr. Kenton is not qualified to render opinions regarding the chemical and biomechanical properties of the TVT devices and/or its components that she proffers in any of her expert reports or in her deposition testimony and such should be excluded in full.

2. Each of Dr. Kenton's Opinions That There is No Discernable Difference Between Laser-cut and Mechanical-cut TVT Devices Should Be Excluded Because She Relied on Data That Is Irrelevant and Unreliable to Support Her Opinions.[13]

Plaintiffs moved this Court to exclude each and every one of Dr. Kenton's opinions that no differences exist between TVT devices that are mechanical-cut and those that are laser-cut because she is unqualified to proffer them. (*See supra* 7-8.) Plaintiffs, likewise, move to exclude any and all such opinions because Dr. Kenton supports them with data that is irrelevant and unreliable to support them.

In fulfilling its role as gate keeper regarding the admissibility of expert testimony, district courts are charged with determining that an expert's testimony is both relevant and reliable. *See Kumho Tire Co.*, 526 U.S. at 152; *see also Cooper*, 259 F.3d at 199 ("Under [Rule] 702, trial judges act as gate keepers to ensure that any and all scientific testimony . . . is not only relevant, but reliable.") (internal citations and quotations omitted.) Additionally Rule 702 *specifically requires* that "the testimony is based on sufficient facts or data." Rule 702(b). Dr. Kenton's reliance materials regarding mechanical-cut and laser-cut mesh miss these reliability and relevance marks by considerable measure and her opinions must be excluded.

[13] Plaintiffs likewise move to exclude any and all similar or identical opinions regarding Ethicon's TVT-O device.

Dr. Kenton stated during her deposition that she had ***no*** available data with which to compare the laser-cut TVT with the mechanical-cut device. Instead, she admitted that she actually referenced data concerning a laser-cut sling device manufactured by another company as a comparison to the mechanical-cut, Ethicon-manufactured TVT-O:

> Q. . . . So why would you use a paper that's comparing the erosion rates of an Ob-Tape laser-cut to a TVT-O mechanical-cut to support your position that there is no difference between the TVT Retropubic mechanically-cut and the TVT-laser-cut?
>
> A. Because there are very few data about actually mechanically-cut versus laser cut, and that's about as good as the data is going to get.

(Ex. B, 427:7-15.)

Further, Dr. Kenton admitted that the non-Ethicon manufactured Ob-Tape device that she used in comparison was markedly different from the TVT devices because the Ob-Tape has higher erosion rates. (*Id*., 426:24-427:6.) Perhaps inevitably, Dr. Kenton finally had to conclude the following during her deposition testimony:

> Q. Do you believe that a study comparing an OB-Tape laser-cut group to a mechanically-cut TVT-O group is an appropriate comparison of data to use when trying to determine the clinical performance difference between the TVT-R mechanical-cut and the TVT-R laser-cut?
>
> A. I don't believe that there are any compelling data to use to compare those two.
>
> Q. Okay. Including this 2006 study that you cite, correct?
>
> A. Correct. It's the only one that's out there---
>
> Q. Thank you.
>
> A. ---which is why I included it.

(*Id*., 429:4-9, 13-20.)

Clearly, Dr. Kenton did not support her opinions with reliable data and they must be excluded. At its most basic, the district court bears the responsibility to determine that "an expert employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *See Cooper*, 259 F.3d at 200 (citing to *Kumho Tire Co. Ltd. V. Carmicha*el, 526 U.S. 137, 152 (1999). (internal quotation omitted.) In making such a determination, the court must find that an expert's testimony is grounded upon '''more than subjective belief or unsupported speculation,''' *Zellers v. Nox Tech Northeast, LLC,* No. 12-2267, 2013 WL 3722346 at *4 (4th Cir. July 17, 2013) (citing to and quoting from *Daubert*, 509 U.S. at 590) and should exclude proffered expert testimony that has a greater potential to mislead than to enlighten. *See Pharmanetics v. Aventis Pharmaceuticals, Inc*., 182 Fed. App'x 267, 273 (4th Cir. 2006). The testimony now before the Court violates this standard on all fronts: it is not of the type that experts practicing in the field would typically rely upon; it constitutes little more than personal opinion on Dr. Kenton's part since, as is nearly axiomatic, one cannot compare the proverbial apples to oranges and expect to derive meaningful conclusions; and it will certainly mislead the jury who cannot be expected to comprehend fully the crucial differences between manufacturers' mesh devices.

Dr. Kenton's opinions regarding mechanical-cut and laser-cut TVTs also run counter to Daubert's relevance standard because it will not assist the trier of fact. *See Daubert*, 509 U.S. at 591. It is nearly impossible to see how evidence regarding a product not in any way at issue in this case would assist the jury to understand the TVT device that is at the center of this litigation.

3. Dr. Kenton's Opinion that the TVT Device Only Causes Chronic Pelvic Pain "Rarely" Must Be Excluded Because She Has Employed Flawed Methodology to Support it.[14]

To be admitted, a court must determine that an expert has arrived at her opinions using valid methodology. *See Daubert*, 509 U.S. at 593-94; *Cooper*, 259 F.3d at 199. Dr. Kenton significantly downplays the chronic pain that women suffer after implant of TVT devices, labelling such pain as only "rare complications". (See Ex. A, 15.) Dr. Kenton's opinions that TVT devices do not often cause chronic pain are not supported by the required methodology and apparently are mostly matters of her personal opinion, thereby requiring their exclusion. *See Zellers*, 2013 WL 3722346 at *4 (expert testimony that is founded only in subjective belief or unsupported speculation must be excluded).

First, Dr. Kenton admitted during her deposition that her opinions about chronic pain could not possibly be grounded in her clinical experience. In fact, she testified that it is typically impossible to determine if vaginal pain is being caused by a medical device or by muscular tenderness:

> It's hard to do --I will--it's hard to distinguish if it's the foreign body or it is the muscle that's causing that pinpoint tenderness frequently.

(Ex. B, 379:6-9.)

Second, Dr. Kenton testified that episodes of chronic pain from implanted mesh devices are, in fact, reported in the same highly-regarded "Level 1" scholarship that she uses to support a great percentage of the other opinions in the Kenton Report:

> Q. The chronic pelvic pain that you talk about that has a very discrete diagnosis, have you seen that reported in the medical literature associated with the TVT?

[14] Plaintiffs now move to exclude any and all similar or identical opinions regarding Ethicon's TVT-O device.

A. Yes

Q. The chronic pelvic pain -- and is that Level 1 evidence that you have seen?

A. Yeah, it does fall into some of the randomized controlled trial data.

(*Id.*, 383:7-15.)

Yet, Dr. Kenton discounts this data concerning pain, and other like it, as articulated by the authors of the highest level of academic medical literature available to her. Instead, she summarily, and without explanation, draws the opposite conclusion to these highly-regarded sources and opines that the TVT device is only very rarely associated with chronic pain. Such will not pass muster under *Daubert* or Rule 702. Dr. Kenton's opinions are not grounded in appropriate methodology and must be excluded.

4. Dr. Kenton's Opinions Regarding Materials She Has Not Read Must Be Excluded in Full.

During her deposition, Dr. Kenton was asked whether she had read an article authored by Dr. Jerry Blaivas entitled, "Safety Considerations for Synthetic Sling Surgery." ("Blaivas article") (Ex. B, 242:23-243:2 [note that the Blaivas article is Exhibit 11 to the Kenton Deposition].) Despite readily, and repeatedly, testifying that she had not read Dr. Blaivas's article (*id*, 243: 4-5; 281: 5-6), Dr. Kenton, nevertheless, proceeded to proffer opinions both about the article and about its source materials. (See *Id*, 278:24-291:10; 292:13-295:11; 300:16-312:2; 317:3-318:19; 341:13-342:17.) Any and all of her opinions concerning the Blaivas article and/or its source materials (at least as insofar as they are related to the Blaivas article) must be excluded as a matter of law.

Rule 702(b) requires that an expert witness's testimony be "based on sufficient facts or data." *See* Rule 702(b); *see e.g. In re Fosamax Products Liability Litig.*, 645 F. Supp. 2d 164, 197 (S.D.N.Y. 2009) (court excluding expert testimony about defendant manufacturer's marketing of the drug at issue where the expert never read the manufacturer's marketing materials, only

skimmed them for an hour, could not recall them in detail, and stated that his knowledge of the manufacturer's marketing came from discussions with colleagues.). Since she admittedly never read the Blaivas article, it is beyond dispute that Dr. Kenton cannot now reasonably claim that any opinions she has about it are grounded in the "sufficient facts or data" required by law. *See* Rule 702(b). Consequently, all of her opinions pertaining to the Blaivas article must be excluded.

B. DR. KENTON LIMITED SOME OF HER OPINIONS CONCERNING BOTH THE TVT AND THE TVT-O DEVICES DURING HER DEPOSITION OF MARCH 25, 2016 AND CANNOT NOW OFFER CONTRADICTORY OPINIONS AT TRIAL.

Dr. Kenton cannot testify at trial in such a way that contradicts, backtracks from, or counters opinions proffered during her sworn testimony at her depositions. Dr. Kenton's testimony during her deposition of March 25, 2016 limited in key respects some of her opinions proffered in the Kenton Report 2 particularly regarding the TVT-O device. Dr. Kenton's deposition testimony of March 25, 2016 also provides important insight into her opinions on the TVT-O device. Dr. Kenton must now testify at trial that:

- the retropubic surgical approach of implanting a mesh device is more likely to cure SUI; (Ex. C, 8:6-22) (limiting the opinion in the Kenton Report 2 that suggests that both the TVT and TVT-O "have a good safety and efficacy profile for treatment of stress incontinence in women.") (Ex. D, 14, point 5.);
- she has removed dozens of TVT-O devices in her clinical practice as a result of complications with them; (*id*, 14:7-14.)
- she is unaware of any clinical trials conducted by Ethicon, itself, to assess the safety of its TVT-O devices; (Ex. C, 22:11-19.)(limits her opinions throughout her expert reports, and deposition testimony, that Ethicon knew its TVT-O devices were safe);

- unique complications are present with the TVT-O and that she does not know with certainty if those problems are caused by the TVT-O devices, themselves, or by issues with the anatomical space where they are implanted in the body; (*id*, 24:7-19)(quoting 24:12-18: "I think that there are unique complications associated with the transobturator route of sling placement that differ from the retropubic. I don't know if it's from the trocar or the sling or if I just took a surgical instrument and put it through that space it would be different.") This deposition testimony renders speculative her opinions that any complications with the TVT-O are caused by the location in the body where the devices are placed and not because of problems with the devices, themselves; (*id*, 25:17-23; 55:8-9; 56:5-8; 112:2-10), and must be excluded; *see Huskey v. Ethicon, Inc.*, 29 F.Supp.3d 691, 702 (S.D.W.Va 2014)(expert opinion must be grounded in more than speculation.)
- it is a "good idea" for the Food and Drug Administration ("FDA") to reclassify urogynecologic surgical mesh instrumentation from Class I to Class II, thereby imposing pre-market notification requirements on the devices; (Ex. C, 27:16-28:24.)
- one flaw with the TVT-O device is that there is not a good method to tension it properly causing voiding dysfunction and other complications in women receiving the implants; (*id*, 37:14-43:7.)
- the aforementioned issues with tensioning the TVT-O could be due to a flaw in the device's design; (*id*, 42:7-43:2.)
- mesh in the pelvic region causes complications, in and of itself, which are not related either to surgical approach or to the location in the body where the implant

is placed; (*id*, 58:16-19) (Q. "And that mesh in the whole pelvic region, that can cause certain complications for women, correct? A. Correct.");

- a flaw in any studies of the TVT-O is that the study period is too short; (*id*, 83:1-2.)
- both Burch and autologous facial sling procedures are appropriate alternatives to the TVT-O and do not carry the same risks of leg and groin pain; (*id*, 101:12-19; 117:14-21.)
- the Instructions For Use ("IFU") for the TVT and the TVT-O devices fail to distinguish between the unique complications and risks for each device; and (*id*, 132:23-133:14; 135:13-22.)
- the IFU for the TVT-O did not warn doctors of the risk of chronic leg pain from the product. (*Id*, 136:4-13.)

V. CONCLUSION

For reasons of the forgoing, the opinions of Dr. Kenton, as set forth herein, must be excluded as they do not meet the standard governing expert opinion set forth by federal law.

Date: April 21, 2016.

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CERTIFICATE OF SERVICE

I hereby certify that on April 21, 2016, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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